

(70179)

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Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

RELATED PROTOCOLS

Intensity-Modulated Radiotherapy of the Prostate

Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> Who are considering initial treatment for localized prostate cancer 	Interventions of interest are: <ul style="list-style-type: none"> Whole gland cryoablation 	Comparators of interest are: <ul style="list-style-type: none"> Radiotherapy Radical prostatectomy Active surveillance 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Disease-specific survival Symptoms Functional outcomes Quality of life Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> Who need salvage treatment for recurrence of localized prostate cancer following radiotherapy 	Interventions of interest are: <ul style="list-style-type: none"> Whole gland cryoablation 	Comparators of interest are: <ul style="list-style-type: none"> Radical prostatectomy Brachytherapy 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Disease-specific survival Symptoms Functional outcomes Quality of life Treatment-related morbidity

DESCRIPTION

Cryoablation, also known as cryotherapy or cryosurgery, is a procedure that attacks cancer cells using extremely cold gas. This technique can be used to treat prostate cancer by percutaneously inserting thin, needle-like cryoprobes into the prostate gland and then sending very cold gas down the cryoprobes to rapidly freeze and thaw the tissue, causing necrosis. This protocol evaluates evidence on the use of total (whole gland, definitive therapy) cryoablation.

SUMMARY OF EVIDENCE

For individuals who are considering initial treatment for localized prostate cancer who receive whole gland cryoablation, the evidence includes several systematic reviews, 2 randomized controlled trials, and many comparative and noncomparative observational studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. High-quality data comparing cryoablation with external-beam radiotherapy, radical prostatectomy, or active surveillance are lacking, but available data have suggested similar overall survival and disease-specific survival rates compared with radical prostatectomy and external-beam radiotherapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have salvage treatment for a recurrence of localized prostate cancer following radiotherapy who receive whole gland cryoablation, the evidence includes primarily noncomparative case series and a few retrospective studies comparing salvage cryoablation with salvage prostatectomy. Relevant outcomes are overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. High-quality data comparing cryoablation with prostatectomy was mixed, and evidence comparing cryotherapy with brachytherapy is lacking. Men in this group have few options and prostatectomy can be difficult in tissue that has been irradiated. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

POLICY

Whole gland cryoablation of the prostate may be considered **medically necessary** as treatment of clinically localized (organ-confined) prostate cancer when performed

- As initial treatment or
- As salvage treatment of disease that recurs following radiotherapy.

MEDICARE ADVANTAGE

For Medicare Advantage, cryosurgery of the prostate gland, also known as cryosurgical ablation, is considered **medically necessary** as primary treatment for patients with clinically localized prostate cancer, Stages T1-T3.

Salvage cryosurgery of the prostate after *radiation failure*, for recurrent cancer, is **medically necessary** for those patients with localized disease who:

1. Have failed a trial of radiation therapy as their primary treatment; and
2. Meet one of the following conditions: Stage T2B or below, Gleason score less than 9, PSA less than 8 ng/mL.

Cryosurgery as salvage therapy is **investigational** after failure of other therapies as the primary treatment.

Cryosurgery as salvage is only **medically necessary** after the failure of a trial of radiation therapy, under the conditions noted above.

BACKGROUND

PROSTATE CANCER

Prostate cancer is the most commonly diagnosed cancer and the third leading cause of cancer deaths among men in the U.S., with an estimated 161,360 new cases and 26,730 deaths in 2017.¹ The diagnosis and grading of prostate cancer are performed by taking a biopsy of the prostate gland.

Treatment

Whole gland (also known as total) cryoablation is one of several methods used to treat clinically localized prostate cancer and may be considered an alternative to radical prostatectomy or external-beam radiotherapy. Additionally, whole gland cryoablation may be used for salvage of nonmetastatic relapse following initial therapy for clinically localized disease. Using percutaneously inserted cryoprobes, the glandular tissue is rapidly frozen and thawed to cause tissue necrosis. Cryosurgical ablation is less invasive than radical prostatectomy and recovery time may be shorter. External-beam radiotherapy requires multiple treatments, whereas cryoablation usually requires a single treatment.

REGULATORY STATUS

Cryoablation of prostate cancer is a surgical procedure that uses previously approved and available cryoablation systems; and as a surgical procedure, it is not subject to regulation by the U.S. Food and Drug Administration.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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